REMARKS

Cancellation of Claims 18-23, 25-33, 35-48, 58-59 and 66-72 and Withdrawal of Claims 34, 46, 49-57 and 60-65 in Response to Restriction Requirement

In the February 12, 2002 Office Action, the Examiner imposed a twelve way restriction requirement against claims 1-72 and required election of one of the following groups:

Group 1 (claims 1-17 and 24) drawn to a chimeric polypeptide wherein the polypeptide is selected from Retroviridae (HIV, SIV, FIV, FeLV), classified in class 424, subclass 207.1;

Group 2 (claims 1-5, 10-17 and 24) drawn to a chimeric polypeptide wherein the polypeptide is selected from Parvoviridae (FPV = feline panleukemia virus), classified in class 424, subclass 233.1;

Group 3 (claims 1-5, 10-17 and 24) drawn to a chimeric polypeptide wherein the polypeptide is selected from Herpesviridae, classified in class 424, subclass 229.1;

Group 4 (claims 18-23) drawn to a chimeric polypeptide which contains a third heterologous domain, classified in class 424, subclass 193.1;

Group 5 (claims 25-28) drawn to a polynucleotide encoding a chimeric polypeptide, classified in class 536, subclass 23.4;

Group 6 (claims 29-33) drawn to an antibody to the chimeric polypeptide, classified in class 530, subclass 388.3;

Group 7 (claims 34-43 and 45) drawn to a method of administering an effective amount of a chimeric polypeptide to achieve antibody production, classified in class 800, subclass 3;

Group 8 (claims 34-43 and 45) drawn to a method of administering an effective amount of a polynucleotide encoding the chimeric polypeptide to achieve antibody protection, classified in class 800, subclass 3;

Group 9 (claims 38 and 44) drawn to a method of administering an effective amount of a chimeric polypeptide to achieve a CTL response, classified in class 800, subclass 3;

Group 10 (claims 38 and 44) drawn to a method of administering an effective amount of a polynucleotide encoding the chimeric polypeptide to achieve a CTL response, classified in class 800, subclass 3;

Group 11 (claims 46-65) drawn to a method of identifying an agent that inhibits an interaction between the virus and a co-receptor of the virus and a receptor, classified in class 436, subclass 501; and

Group 12 (claims 66-72) drawn to a method of identifying an agent that inhibits viral infection of a cell, classified in class 435, subclass 7.1;

Applicants hereby affirm the prior provisional election of Group I including claims 1-17 and 24 made on March 12, 2002.

Correspondingly, applicants cancel claims 18-23, 25-33, 35-48, 58-59 and 66-72 and acknowledge the withdrawal of non-elected of claims 34, 46, 49-57 and 60-65 from consideration, with the intent to rejoin claims 34, 46, 49-57 and 60-65 at a later time, or alternatively, with reservation of the right to file divisional application(s) directed to the subject matter of those claims if rejoinder is not effected.

Specifically, applicants intend to rejoin the withdrawn method claims 34, 46, 49-57 and 60-65 when the elected product claims 1-17 and 24 (as herein amended, and as may subsequently be further amended) are determined to be allowable. Such rejoinder would be fully proper under these circumstances, for the following reasons:

When an application as originally filed discloses a product and the process for making and/or using such product, and only the claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product for examination through rejoinder procedure in accordance with MPEP §821.04, provided that the process claims depend from or include all the limitations of the allowed product claims.

In the present application the elected claims 1-17 and 24 are directed to a product (chimeric polypeptide) and the non-elected withdrawn claims 34, 46, 49-57 and 60-65 are directed to methods for using the product recited in claims 1-17 and 24. The withdrawn non-elected method claims 34, 46, 49-57 and 60-65 as amended herein recite **all the limitations included in the elected product claims** 1-17 and 24. Consistent with the provisions of the MPEP §821.04, if

product claims 1-17 and 24 are subsequently found allowable, the withdrawn method claims 34, 46, 49-57 and 60-65 may be rejoined for examination.

Applicants, therefore, request the Office to take up the non-elected method claims 34 and 46-65 for examination when product claims 1-17 and 24 are found allowable. Consistent with such intent to rejoin, applicants have amended method claims 34 and 46, notwithstanding the Office's withdrawal of such claims, to present them in form suitable for future examination upon their rejoinder with the allowed elected claims.

Rejections of Claims and Traversal Thereof

In the April 23, 2002 Office Action,

claims 1-17 and 24 were rejected under 35 U.S.C. §112, second paragraph;

claims 1 and 17 were rejected under 35 U.S.C. §112, first paragraph;

claims 1 and 24 were rejected under 35 U.S.C. §102(b) as anticipated by Chackerian, et al. (Proceedings of the National Academy of Sciences, March 1999);

claims 1-8, 10-11 and 24 were rejected under §102(b) as anticipated by U.S. Patent No. 5,518,723 (DeVico, et al.) or U.S. Patent No. 5,843,454 (DeVico, et al.); and

claims 1-8, 10-11 and 24 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 and 3 of U.S. Patent No. 5,518,723 (DeVico, et al.) and claim 1 of U.S. Patent No. 5,843,454 (DeVico, et al.).

The foregoing rejections of the claims 1-17 and 24 are hereby traversed, in application to the claims as amended herein, and reconsideration of the patentability of amended claims 1-17 and 24 is requested, in light of the ensuing remarks.

Rejections under 35 U.S.C. §112, second paragraph

Claims 1-17 and 24 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claiming the subject matter which applicants regard as the invention.

According to the Office, it is unclear in claim 1 what is meant by "bind each other." Applicants have amended independent claim 1 to more clearly define the claimed invention. The claimed chimeric polypeptides of the present invention include a virus coat polypeptide sequence and viral receptor polypeptide sequence each of which is linked to an amino acid sequence that acts as a spacer therebetween (see page 13, lines 17-19 of the present application). As stated in the present application at page 8, lines 17-21 and page 14, lines 10-13, the spacer is of sufficient length to allow the virus coat polypeptide sequence and the viral receptor polypeptide sequence to form a folded and interacting complex. As such, the inclusion of the amino acid sequence between the two peptides allows for the folding of the single-chain molecule to form an interacting complex that can be used to generate antibodies, such as discussed in the present application at page 44, lines 13-15; and bind to a co-receptor, such as discussed at page 46, lines 21-23.

According to the Office, it is unclear in claim 1 what is meant by "chimeric polypeptide." For purposes of this invention, applicants have included a definition for "chimeric polypeptide," as appearing in the specification and the claims, at page 13, lines 14-16 wherein it is described that "[c]himeric polypeptide refers to an amino acid sequence having two or more parts which generally are not found together in an amino acid sequence in nature." Case law supports the position that an applicants have the right to define terms that are included in the best mode operation of their invention. The Court in *Intellicall Inc. V. Phonometrics Inc.*, 952 F.2d 1384, 21 USPQ2d 1383 (CAFC 1992), citing *Lear Siegler, Inc. v. Aeroquip Corp.*, 221 USPQ 1025, 1031 (Fed Cir. 1984) stated:

> "So long as the meaning of an expression is made reasonably clear and its use is consistent within a patent disclosure, an inventor is permitted to define the terms of his claims. Nevertheless, the place to do so is in the specification of the inventor's application, and the time to do so is prior to that application

> acquiring its own independent life as a technical disclosure through its issuance as a United States patent."

Applicants meet this standard. One having ordinary skill in the art would understand the meaning of a "chimeric polypeptide" by analyzing the claims in light of the specification, and by following the teachings of the specification which here adequately teach the specifics of the claimed chimeric polypeptides.

Based on the foregoing arguments and the amendments presented herein, applicants have overcome all 35 U.S.C. §112, second paragraph rejections, and request that the Office withdraw such rejections.

Rejection under 35 U.S.C. §112, first paragraph

Claims 1 and 17 were rejected under 35 U.S.C. §112, first paragraph. Applicants have amended claim 1 and canceled claim 17 thereby obviating this rejection. As such, applicants request the withdrawal of such rejection.

Rejections under 35 U.S.C. §102(b)

Claims 1 and 24 were rejected under 35 U.S.C. §102(b) as anticipated by Chackerian, et al. Applicants respectfully traverse this rejection and submit that applicants' claimed invention, as amended herein, is not anticipated by the cited reference.

Applicants have amended claim 1 to recite:

> **1. A chimeric polypeptide comprising:**
> **a virus coat polypeptide sequence, wherein the virus is an immunodeficiency virus selected from the group consisting of HIV, SIV, FIV, and FeLV, and a viral receptor polypeptide sequence, wherein the virus coat polypeptide sequence and the receptor polypeptide sequence are each linked to a spacer consisting of an amino acid sequence of sufficient length to allow the virus coat polypeptide**

sequence and the viral receptor polypeptide sequence to form a folded complex.

The Chackerian, et al. reference discloses a chimeric L1-CCR5 peptide containing the BPV-1 L1 peptide and mouse CCR5 receptor peptide, but does not disclose, teach or suggest that the **"the virus coat polypeptide sequence and the receptor polypeptide sequence are each linked to a spacer consisting of an amino acid sequence of sufficient length to allow the virus coat polypeptide sequence and the viral receptor polypeptide sequence to form a folded complex."** as claimed by applicants.

Anticipation under 35 U.S.C. §102 requires that "each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros., Inc. v. Union Oil Co.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Further, anticipation requires the presence in a single prior art reference of each and every element of the claimed invention, ***arranged as in the claim.*** *Lindermann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984) (emphasis added). **The Chackerian, et al. reference does not meet this standard.** Thus, claim 1, as amended herein, is not anticipated by Chackerian, et al. Applicants request that this rejection be withdrawn.

Claims 1-8, 10-11 and 24 were rejected under §102(b) as anticipated by U.S. Patent No. 5,518,723 (DeVico, et al., hereinafter DeVico '723)) or U.S. Patent No. 5,843,454 (DeVico, et al., hereinafter DeVico '454). Applicants respectfully traverse this rejection and submit that applicants' claimed invention is not anticipated by the cited references.

Both the DeVico references disclose a gp120-CD4 complex with no disclosure regarding inclusion of an amino acid sequence spacer between the gp 120 peptide and the CD4 peptide. As a matter of fact it is expressly stated in DeVico '454 that the N-terminus of CD4 reacts with gp120 (see column 11, lines 11-12). One skilled in the art would recognize that the gp120 portion binds directly with the CD4. Clearly, neither cited reference discloses, teaches or suggests a chimeric polypeptide that is a linear sequence of a virus coat polypeptide sequence and a receptor polypeptide sequence linked by an amino acid sequence spacer therebetween. This additional spacer provides for sufficient flexibility in the chimeric polypeptide of the

present invention to allow the option of folding of the chimeric polypeptide. Neither of the DeVico references meet the statutory requirements of an anticipating reference because each and every element of the claimed invention, arranged as in the present claims, is not found in the cited reference. Applicants submit that claims 1-8, 10-11 and 24 are not anticipated by either DeVico reference and, therefore, are in condition for allowance.

Rejection Under the Judicially Created Doctrine of Obviousness-Type Double Patenting

Claims 1-8, 10-11 and 24 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 and 3 of U.S. Patent No. 5,518,723 (DeVico, et al., hereinafter DeVico '723) and claim 1 of U.S. Patent No. 5,843,454 (DeVico, et al., hereinafter DeVico '454). This ground of rejection is respectfully traversed.

The initial burden of establishing a *prima facie* basis to deny patentability to a claimed invention is always upon the examiner. *In re Oetiker*, 977 F.2d 1443,24 USPQ 1443, (Fed. Cir. 1992). The test for obviousness-type double patenting is whether the claimed invention of the subject application would have been obvious from the subject matter of the **claims** in the 'DeVico '723 and DeVico '454 patents. *See In re Longi*, 774 F.2d 1100, 225 USPQ 645 (Fed.Cir. 1985). It should be understood that the Office is not at liberty to resort to the text of the 'DeVico '723 and DeVico '454 specification for additional facts to support the obviousness-type double patenting. In all instances, only the literal statement of claims 1 and 3 of 'DeVico '723 and claim 1 of DeVico '454 may be considered in arriving at the conclusion of obviousness.

Applicants submit that claims 1 and 3 of 'DeVico '723 and claim 1 of DeVico '454 differ greatly from claims 1-8, 10-11 and 24 in the subject application by reciting *inter alia*, the addition of a spacer consisting of an amino acid sequence that links the virus coat polypeptide sequence and the receptor polypeptide sequence.

Applicants contend that it is patentably distinct to include a spacer consisting of an amino acid sequence between the virus coat polypeptide sequence and the receptor polypeptide especially when **neither the claims nor full texts** of the 'DeVico '723 and DeVico '454 references **teach or suggest such an amino acid sequence spacer**. Because the Office has not provided the

applicants with any factual basis and/or rationale to support the conclusion that the claimed invention is an obvious variation of the previously patented invention the double patenting rejection of claims 1-8, 10-11 and 24 cannot stand. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Appointment of New Attorney of Record

Applicants have included herewith in **APPENDIX C** a "REVOCATION OF POWER AND AUTHORITY OF PREVIOUSLY APPOINTED PATENT ATTORNEYS/AGENTS OF RECORD, AND APPOINTMENT OF NEW ATTORNEYS/AGENT OF RECORD" to revoke any and all previous Powers of Attorney in this application; and appoint the following Steven J. Hultquist, Reg. No. 28,021; Marianne Fuierer, Reg. No. 39,983 and Janet Elliot, Reg. No. 33,594, with full powers of appointment, substitution and revocation, to prosecute this application and all continuations and divisions thereof, and to transact all business in the United States Patent and Trademark Office connected with such applications and patent(s) hereafter issuing thereon:

Please forward all further correspondence in connection with this application to:

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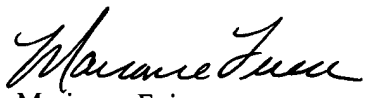
Conclusion

Applicants have satisfied all the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Winkler reconsider the patentability of claims 1-3, 6-16 and 24 in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly solicited. In the event that any issues remain, Examiner Winkler is requested to contact the undersigned attorney at (919) 419-9350 to resolve same.

Respectfully submitted,



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APPENDIX A

Please amend claims 1, 6, 7, 34 and 46 as follows:

1. A chimeric polypeptide comprising:
a virus coat polypeptide sequence, wherein the virus is an immunodeficiency virus selected from the group consisting of HIV, SIV, FIV, and FeLV, and a viral receptor polypeptide sequence, wherein the virus coat polypeptide sequence and the receptor polypeptide sequence are each linked [by] to a spacer consisting of an amino acid sequence of sufficient length to allow [and wherein] the virus coat polypeptide sequence and the viral receptor polypeptide sequence to form a folded complex[bind to each other].

6. The chimeric polypeptide of claim [5] 1, wherein the HIV is HIV- 1 or HIV-2.

7. The chimeric polypeptide of claim [5] 1, wherein the HIV is a macrophage tropic or a lymphocyte tropic HIV.

Amended Method Claims to be Rejoined

34. A method for producing an antibody that binds to the chimeric polypeptide of claim 1, comprising administering the chimeric polypeptide of claim 1 to a subject [, or a polynucleotide that encodes the chimeric polypeptide of claim 1,] in an amount sufficient for the subject to produce antibody to the chimeric polypeptide of claim 1.

46. A method for identifying an agent that inhibits an interaction between a virus and a virus co-receptor comprising the steps of:

(a) contacting the chimeric polypeptide of claim [3] 1 with a virus co-receptor under conditions allowing the chimeric polypeptide and the co-receptor to bind, in the presence and absence of a test agent; and

(b) detecting binding in the presence and absence of the test agent, wherein decreased binding in the presence of the test agent thereby identifies an agent that inhibits binding between the virus and the virus co-receptor.

APPENDIX B

All Pending Claims

1. A chimeric polypeptide comprising:
a virus coat polypeptide sequence, wherein the virus is an immunodeficiency virus selected from the group consisting of HIV, SIV, FIV, and FeLV, and a viral receptor polypeptide sequence, wherein the virus coat polypeptide sequence and the receptor polypeptide sequence are each linked to a spacer consisting of an amino acid sequence of sufficient length to allow the virus coat polypeptide sequence and the viral receptor polypeptide sequence to form a folded complex.

2. The chimeric polypeptide of claim 1, wherein the virus is a virus having an envelope polypeptide.

3. The chimeric polypeptide of claim 1, wherein the virus is a virus that binds a co-receptor polypeptide.

6. The chimeric polypeptide of claim 1, wherein the HIV is HIV- 1 or HIV-2.

7. The chimeric polypeptide of claim 1, wherein the HIV is a macrophage tropic or a lymphocyte tropic HIV.

8. The chimeric polypeptide of claim 2, wherein the envelope polypeptide comprises a gp 120 polypeptide sequence.

9. The chimeric polypeptide of claim 8, wherein the gp120 polypeptide sequence lacks 60 amino acids from the amino terminus and 20 amino acids from the carboxyl terminus.

10. The chimeric polypeptide of claim 1, wherein the receptor is a CD4 polypeptide sequence.

11. The chimeric polypeptide of claim 10, wherein the CD4 polypeptide sequence comprises the Dl and D2 domains.

12. The chimeric polypeptide of claim 1, wherein the spacer is an amino acid sequence.

13. The chimeric polypeptide of claim 1, wherein the spacer has from about 5 to about 200 amino acids.

14. The chimeric polypeptide of claim 1, wherein the spacer has from about 10 to about 100 amino acids.

15. The chimeric polypeptide of claim 1, wherein the spacer has from about 15 to about 50 amino acids.

16. The chimeric polypeptide of claim 1, wherein the spacer has from about 20 to about 40 amino acids.

24. The chimeric polypeptide of claim 1, further comprising a pharmaceutically acceptable carrier.

Method Claims to be Rejoined

34. A method for producing an antibody that binds to the chimeric polypeptide of claim 1, comprising administering the chimeric polypeptide of claim 1 to a subject in an amount sufficient for the subject to produce antibody to the chimeric polypeptide of claim 1.

46. A method for identifying an agent that inhibits an interaction between a virus and a virus co-receptor comprising the steps of:

(a) contacting the chimeric polypeptide of claim 1 with a virus co-receptor under conditions allowing the chimeric polypeptide and the co-receptor to bind, in the presence and absence of a test agent; and

(b) detecting binding in the presence and absence of the test agent, wherein decreased binding in the presence of the test agent thereby identifies an agent that inhibits binding between the virus and the virus co-receptor.

49. The method of claim 46, wherein the test agent is added after contacting the chimeric polypeptide with the virus co-receptor.

50. The method of claim 46, wherein the test agent is added before contacting the chimeric polypeptide with the virus co-receptor.

51. The method of claim 46, wherein the test agent is a library of agents.

52. The method of claim 46, wherein the test agent is selected from the group consisting of a peptide, an organic molecule, an antibody, an antiviral, an immunodeficiency virus co-receptor or functional fragment thereof.

53. The method of claim 47, wherein the immunodeficiency virus co-receptor is a CCR5 or CXCR4 polypeptide sequence.

54. The method of claim 46, wherein the virus co-receptor is present on the surface of an intact cell.

55. The method of claim 54, wherein the intact cell is present in an animal.

56. The method of claim 55, wherein the animal is a non-human primate.

57. A method for identifying an agent that inhibits an interaction between a virus and a virus receptor comprising the steps of:

a) contacting the chimeric polypeptide of claim 1 with a test agent; and

b) detecting binding between the virus coat polypeptide sequence and the viral receptor polypeptide sequence, wherein a decreased amount of binding in the presence of the test agent identifies an agent that inhibits binding between the virus and the virus receptor.

60. The method of claim 57, wherein the test agent is added after contacting the chimeric polypeptide with the virus receptor polypeptide.

61. The method of claim 57, wherein the test agent is added before contacting the chimeric polypeptide with the virus receptor polypeptide.

62. The method of claim 57, wherein the test agent is a library of agents.

63. The method of claim 57, wherein the test agent is selected from the group consisting of a peptide, an organic molecule, an antibody, an antiviral, an immunodeficiency virus receptor or functional fragment thereof.

64. The method of claim 58, wherein the immunodeficiency virus receptor polypeptide is a CD4 polypeptide sequence.

65. The method of claim 57, wherein the virus receptor polypeptide is present on the surface of an intact cell.